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In The

# Supreme Court of the United States

October Term, 1972

## No. 72-113

**STERLING DRUG, INC.,**

*Petitioner,*

vs.

**ANNA T. SINGER and LESLIE SINGER,**

*Respondents.*

## BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

### PREFATORY NOTE.

Petitioner, Sterling Drug, Inc., does not set forth any jurisdictional grounds upon which its petition is based. Rather it states its basis is 28 U.S.C. 1254(1). Nowhere is this Court's Rule 19 referred to nor any of the reasons stated therein urged as a basis of jurisdiction.

Actually, the essence of the petition is that the Court of Appeals should have arrived at a different conclusion and should not have exercised its power to remand for trial on the issue of damages only.

## THE QUESTION PRESENTED.

More properly stated the question is: Should this Court interfere with the interlocutory order of the Court of Appeals which on review finds the only issue between the litigants is that of damages?

## REASONS FOR DENIAL OF THE PETITION.

Petitioner's sketchy factual statement requires an addendum.

The uncontradicted proof was:

(a) Aralen causes chloroquine retinopathy;

(b) Mrs. Singer's blindness was due to ingestion of Aralen;

(c) Since 1958, petitioner knew that Aralen caused this condition;

(d) There were multiple cases of serious visual disturbance, including blindness, reported in Aralen users over this period but it was not until February 1963, that petitioner sent a letter to the medical profession. It continued to market this drug.

Petitioner's statement that "the crux of the dispute" (Pn. p. 2) was whether respondent had improperly obtained refills of an original prescription is not only an innuendo but not the fact. Moreover, this could not con-

stitute a defense as a matter of law to this strict liability in tort action.

Its statement that "it was undisputed that plaintiff was suffering from a chronic incurable disease known as lupus erythematosus which can cause blindness . . ." (Pn. p. 2), is incorrect. On the contrary it was uncontradicted testimony of outstanding opthalmologists such as two professors of Opthalmology of the University of Chicago Medical School that the respondent suffered from a chloroquine retinopathy or damage to the retina of the eye caused by the ingestion of Aralen, the trade name for the drug chloroquine. (R. 70, 251, 2462) As the opinion noted: "the defendant failed to connect the movie in this case since there was no testimony that Anna Singer suffered from retinopathy caused by lupus erythematosus rather than chloroquine retinopathy." (Pn. p. 7a)

The want of timeliness of the warning and its insufficiency is apparent from a few facts.

On October 10, 1958, Dr. Bagnall, an experimenter for petitioner, wrote petitioner's Dr. Rice (Pltfs' Ex. 35), describing two cases of visual impairment in Aralen users.

Attached to that letter of Dr. Bagnall was written in handwriting:

> "3/25/60. Do not advise FDA now. Send lit. when reprinted including corneal changes & say it is modified version of what we subm. several months & which they passed on. Discussed w/Dr. Foley & Dr. Rice."

At no time did the defendant explain why this letter of October 10, 1958, was withheld from the Food and Drug Administration.

In the years 1959, 1960, 1961, 1962, 1963, and thereafter medical literature was flooded with reports showing Aralen to be the incriminating factor in loss of vision in its users.

Dr. Foley, petitioner's medical director, as early as June, 1960, (Pltfs' Ex. F 196), prepared a proposed warning concerning retinal changes as the result of Aralen. It did not send out any warning until 1963.

On December 2, 1959, petitioner's Dr. C. H. Roth wrote its Dr. J. B. Rice that an examination of defendant's files revealed instances in which retinal changes were observed in persons taking Aralen. (Pltfs' Ex. 271)

In evidence were memoranda and letters from practicing physicians, petitioner's agents, as well as lay persons, about loss of vision in Aralen users. These commenced in 1958). (Pltfs' Exhibits 174, 329, 331, 338, 342, 344, 315A, 277, 314, 40A, 197 F6.)

The Physicians' Desk Reference is circulated through the medical profession. The particular drug company writes its advertising copy for this important book. (R. 604)

Throughout the years from 1955 to 1961, the Desk Reference's description of Aralen contained no warning whatsoever as to serious visual side effects.

In 1962, when Aralen was a recognized cause of retinal change, petitioner for the first time since 1957, failed to list Aralen although it was marketed.

In 1963, it first listed irreversible changes in the retinae of users. (Pltfs' Exhibit 52)

**THERE WERE NO ISSUES OF FACT ON THE QUESTION OF LIABILITY; PETITIONER DID NOT, AT THE TRIAL, CHALLENGE THE CHARACTER OF THE DRUG AND THE CAUSE OF ANNA SINGER'S BLINDNESS; ITS DEFENSIVE EFFORTS WENT TO HER CONDUCT WHICH COULD NOT, AS A MATTER OF LAW BE A DEFENSE.**

In much of its litigation petitioner has sought to shift its obligation to some third person such as druggist or doctor. (*Sterling Drug, Inc.* v. *Cornish*, 370 F. 2d 82 (8 Cir. 1966); *Kershaw* v. *Sterling Drug, Inc.*, 415 F. 2d 1009, (5 Cir. 1969); *Krug* v. *Sterling Drug, Inc.*, (Mo.) 416 S.W. 2d 143 (1967) and *Schenebeck* v. *Sterling Drug, Inc.*, 291 F. Supp. 368, 423 F. 2d 919 (8 Cir. 1970).)

In *Cornish*, *Kershaw* and *Krug*, the druggist(*) was sought to be interposed as a defense, while in *Schenebeck*, it was the doctor, who had given plaintiff a refillable prescription which was used for four years without medical supervision.

Here, petitioner sought to interpose Anna Singer's conduct as a defense, notwithstanding that assumption of risk under the Indiana controlling law would be the only vehicle of questioning her conduct. There was, admittedly, no evidence of assumption of risk. Petitioner tried this

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(*) In both the *Kershaw* and *Cornish* cases, this instruction was given:

"However, if you believe from the evidence that even though the druggist did not obtain the approval of the individual prescribing doctor for the refilling of such prescriptions, if you also find from the evidence that the doctor knew and authorized the plaintiffs to obtain such refills and continued to treat each plaintiff with the knowledge that she was taking said medicine, then the fact that they may have been refilled by the druggist in violation of the law, would not prevent either plaintiff from recovering if she was otherwise entitled to recover."

case as if it were a negligence action, with contributory negligence an issue.

The Court of Appeals observed: "The Singers proved a stronger case than required since the doctrine of strict liability would hold Sterling liable for manufacturing and marketing, without adequate warning, a dangerously defective product like Aralen." (p. 82)

**MISUSE OF ARALEN.**

The argument concerning misuse is without foundation in law or in fact. Misuse is a use by the consumer which was not reasonably foreseeable. (*Thomas* v. *General Motors*, 91 Cal. Rptr. 301, 306 (1971).)

Obviously taking a drug made to be consumed by such members of the public as the respondent is a foreseeable use.

Dwelling on Anna Singer's conduct, petitioner suggests an issue that her lupus condition was aggravated by her "exposure to hot sun." The Court of Appeals found no evidence to support this contention. (Pn. p. 8a)

Nor was there any evidence of acerbation or remissions of lupus. On the contrary, she had no evidence of this condition for several years. Dr. Tuffanelli did not state lupus could cause retinopathy, as the Court of Appeals points out. (Pn. p. 7a) Dr. Tuffanelli not only failed to express any relationship between Mrs. Singer's eye condition and the lupus condition (R. 2717-18), but said he was not an expert concerning eye conditions. (R. 2123)

Petitioner's comments concerning excessive dosage are interesting. Petitioner on its own label states: "Usual

dose: 2 tablets," and again "Usual dose: 20 to 4 tablets." (Pltfs' Exhibit 11)

Respondent Anna Singer took two tablets daily in accord with these directions.

The Physician's Desk Reference, written by defendant (R. 604), does not refer to dosage as a factor in side effects, even in the 1963 Edition. (Pltfs' Exhibit 52)

The product information card suggesting periodical ophthalmological examinations is immaterial. Dr. Hoit, who prescribed the drug, did not have any of his patients on Aralen obtain eye examinations. (R. 1686-1693) His conduct could not be a defense.

Petitioner's statement that respondent did not see any physician in 1963 before taking a trip, is not only contrary to the record (R. 1360) but immaterial.

**PETITIONER'S DUTY TO PLAINTIFF WAS NON-DELEGABLE; THE CONDUCT OF A THIRD PARTY COULD NOT CONSTITUTE A DEFENSE.**

Dr. Hoit gave Anna Singer a written prescription dated April 29, 1957 (Pltfs' Exhibit 381A) and wrote the referring doctor thanking him for sending Mrs. Singer to him. (Pltfs' Exhibit 409)

Proof of the prescription of the drug (Pltfs' Exhibits 381A, 381B, 416) was made by three pharmacists. (R. 1069, 1074, 1079, 1090, 1091) Dr. Hoit's records were lost in 1963 when a cleaning woman employed by the building erroneously threw them out. (R. 893, 894) He did not recall Mrs. Singer upon being shown the prescription in his longhand or the letter in his handwriting to the forwarding doctor. He could not recall the respondent with-

out records. He made it clear, however, that he did not deny that Mrs. Singer was his patient or that he treated her during 1957, 1958, 1958, 1960, 1961 and 1963 for the lupus condition. (R. 1615, 1616, 1619-21)

Indeed, if Dr. Hoit had given respondent a refillable prescription in 1957 and had never seen her, petitioner could not avoid responsibility for the character of the drug which it described as one which was to be persistently used. (Pltfs' Exhibit 12A) (*Schenebeck* v. *Sterling Drug, Inc.*, 291 F. Supp. 368 (E.D. Ark.), 423 F. 2d 919, 923 (8 Cir. 1970)

There is no intervening cause recognized here (*Zahora* v. *Harnischfeger Corp.*, 404 F. 2d 172, 177 (7 Cir. 1968), construing Indiana Law; *Sterling Drug, Inc.* v. *Cornish*, 370 F. 2d 82, 85 (8 Cir. 1966); *Schenebeck* v. *Sterling Drug, Inc.*, 291 F. Supp. 368, 423 F. 2d 919, 922 (8 Cir. 1970).)

The conduct of the treating doctor has long been recognized as not imputable to the plaintiff in an action against a drug manufacturer. (*Schenebeck* v. *Sterling Drug, Inc.*, 291 F. Supp. 368, 423 F. 2d 919, 922 (8 Cir. 1970); *Kershaw* v. *Sterling Drug, Inc.*, 415 F. 2d 1001, (5 Cir. 1969); *Mochlenbrock* v. *Parke, Davis and Co.*, 141 Minn. 154, 169 N.W. 541, 544 (1918); *Abbott Laboratories* v. *Lapp*, 78 F. 2d 170 (7 Cir. 1935).)

The issues here were the character of the drug and whether it was a proximate cause of respondent's condition of ill-being. (Restatement of the Law of Torts, 402A) Nor was this an unavoidable unsafe product within Comment k of 402A of the Restatement of the Law of Torts. The Court of Appeals discussed this contention at length. (Pn. p. 4a)

**OTHER ARALEN CASES.**

Other Aralen cases are of little assistance because:

(a) The record in each case was different with the defendant in many situations questioning the character of the drug—a strategy not employed here;

(b) The laws of different jurisdictions were involved. This action was governed by Indiana law;

(c) Almost all proceeded on the theory of negligence, while petitioner does not deny the applicability of the doctrine of strict liability in tort;

(d) In a vast majority, the plaintiff recovered and that judgment was affirmed on appeal; and

(e) Different periods of time were involved. Specifically, many cases were tried earlier when the available proof had not existed. As an example, *Krug* v. *Sterling Drug, Inc.*, 416 S.W. 2d 142 (1967), involved the use of the medication as far back as 1953.

*Oppenheimer* v. *Sterling*, 7 Ohio App. 2d 103, 219 N.E. 2d 54, (1964) involved a directed verdict for the defendant.(*) *Oppenheimer* refers to the intervening causal conduct of doctor and druggist but no intervening cause exists here. (*Zahora* v. *Harnischfeger Corp.*, 404 F. 2d 172, 177 (7 Cir. 1968); *Sterling Drug, Inc.* v. *Cornish*, 370 F. 2d 82, 85 (8 Cir. 1966); *Schenebeck* v. *Sterling Drug, Inc.*, 291 F. Supp. 368, 423 F. 2d 919, 922 (8 Cir. 1970).) It is a matter of record that the petitioner settled the case after the Ohio intermediate court opinion.

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(*) In answer to an interrogatory asking for the name of the claimant, the Court, the date of last ingestion, the product and status, defendant responded: "Faye Oppenheimer, Common Pleas Court, Franklin County, Ohio, date of last ingestion November, 1960, Aralen, and under status: Settled—Defendant's verdict affirmed on appeal." (C.R. 70, p. 17)